OVATION™

Abdominal Stent Graft System

Instructions for Use

Humanitarian Device. Authorized by Federal law for use in the treatment of abdominal aortic aneurysms. The effectiveness of this device for this use has not been demonstrated.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

TRIVASCULAR™

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1. Device Description

The TriVascular Ovation™ Abdominal Stent Graft System is an endovascular device delivered via a low-profile catheter to treat abdominal aortic aneurysms (AAAs). The stent graft is designed to reline the diseased vasculature, providing an endovascular blood conduit for isolating the aneurysm from the high pressure flow of blood, thereby reducing the risk of rupture. The stent graft is a modular configuration comprised of an aortic body section, iliac limbs, and iliac extensions as required (Figure 1).

The TriVascular Ovation Abdominal Stent Graft System includes:

- A 20mm Aortic Body Stent Graft and delivery catheter
- Iliac Limb Stent Grafts and delivery catheters
- Iliac Extension Stent Grafts and delivery catheters, as required
- A Fill Polymer Kit
- An Autoinjector

The aortic body is comprised of a proximal stent for suprarenal fixation and a low-permeability PTFE graft. The stent is designed with integral anchors to enable fixation to the aortic wall. For delivery, the stent is in a compressed state within the catheter. When released from the compressed state, the stent expands to engage the vessel wall. The nitinol stent is radiopaque and the implant contains radiopaque markers adjacent to the proximal graft edge. These radiopaque markers serve as positioning aids during placement of the device and allow the implant to be positioned to not obstruct the renal arteries. To seal the proximal end of the graft and to provide support for the aortic body legs into which the iliac limbs are deployed, the graft body contains a network of inflatable rings that are filled with a liquid polymer that solidifies during the deployment procedure. The graft has a fill port that connects the fill network of the graft to the delivery catheter.

The iliac limbs and extensions are comprised of a nitinol stent encapsulated in low-permeability PTFE. The iliac limbs are deployed into the leg section of the aortic body. Radiopaque markers enable the physician to visualize the appropriate iliac limb - aortic body overlap or iliac extension – iliac limb overlap during a catheter-based deployment. Stent radial force provides both fixation and sealing of the interface between the aortic body and each iliac limb, between the iliac limb and iliac extension, and between the iliac limb/extension and its landing zone in the iliac artery.

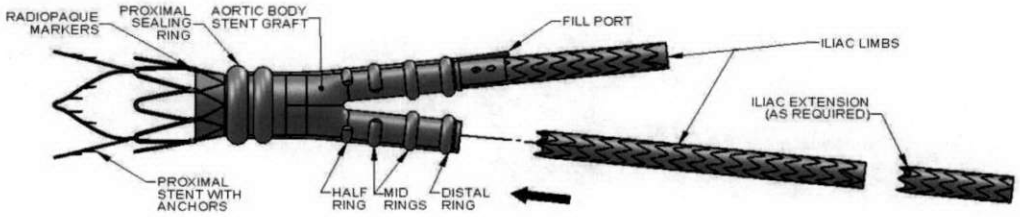


Figure 1. Schematic of Deployed TriVascular Ovation Abdominal Stent Graft System

1.1. Delivery System

To facilitate device introduction into the access vessel, the aortic body, the iliac limbs, and the iliac extensions are preloaded into delivery catheters (14F OD, 13F–14F OD, and 13F–14F OD respectively, as illustrated in Figure 2 and Figure 3). The aortic body is deployed via the aortic body delivery catheter. The aortic body delivery catheter has a lumen that allows for the use of a guidewire to help deliver the stent graft to the deployment site.

During stent graft deployment, the device is first positioned and the sheath is retracted. The proximal stent is then deployed using stent release knobs on the handle. The fill polymer is then delivered through the fill connector port using the Autoinjector.

The contralateral and ipsilateral iliac limbs are each deployed via iliac limb delivery catheters. After deployment of the aortic body, a guidewire is placed from the contralateral access site into the contralateral distal leg of the aortic body. The contralateral iliac limb is advanced into position and deployed into the aortic body by retracting the catheter sheath with the catheter in the appropriate position. The contralateral delivery catheter is then withdrawn from the vasculature. After the fill polymer cures within the sealing rings, the aortic body delivery

catheter is disengaged from the fill port of the graft and withdrawn from the vasculature. The ipsilateral iliac limb delivery catheter is advanced over the ipsilateral guidewire and deployed using the method described above for the contralateral limb. The ipsilateral delivery catheter is then withdrawn from the vasculature.

If an iliac extension is required, the delivery system is advanced over the guidewire and deployed using the method described above for contralateral and ipsilateral iliac limbs.

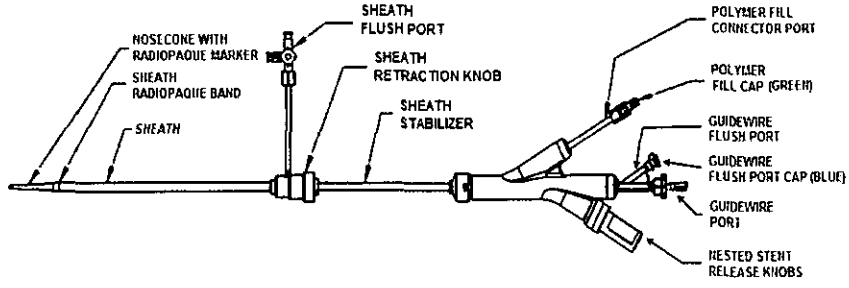


Figure 2. Schematic of TriVascular Ovation Abdominal Stent Graft System Aortic Body Delivery Catheter

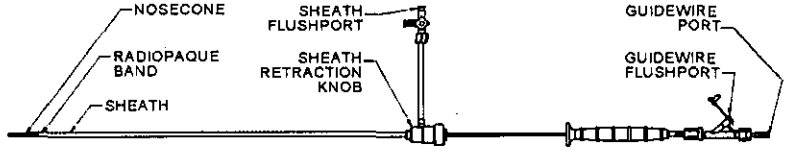


Figure 3. Schematic of TriVascular Ovation Abdominal Stent Graft System Iliac Limb/ Iliac Extension Delivery Catheter

The TriVascular Ovation Abdominal Stent Graft System is designed to accommodate various aortic anatomies, including a range of proximal and distal aortic neck diameters and aneurysm lengths. Refer to **Table 12** for patient sizing information and **Tables 13-15** for product sizes and configurations.

1.2. Fill Polymer and Autoinjector

The Fill Polymer Kit is shown in Figure 4. The Fill Polymer is comprised of three materials that are mixed prior to injection. Upon mixing and injection into the graft, the components form a radiopaque polymer that fills the sealing rings of the PTFE channels in the wall of the aortic body graft. The fill polymer radiopacity dissipates over time and may not be visible on fluoroscopy, X-ray or CT beyond 1-2 months post-implant.

Prior to use, the two valves on the fill polymer kit are opened and the fill polymer is mixed by alternately depressing the two syringe plungers for a minimum of 15 full strokes. Thereafter, the full syringe is disconnected from the connection tube, slipped out of the syringe support and connected to the fill polymer injection port on the catheter handle. The syringe plunger is then inserted into the Autoinjector (Figure 5) and the Autoinjector is given a quarter-turn to lock it in place. The Autoinjector applies controlled pressure to inject the fill polymer into the graft.

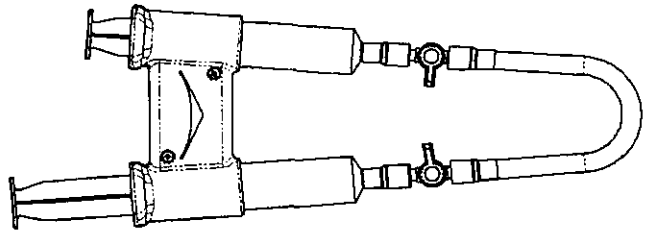


Figure 4. *TriVascular Fill Polymer Kit*

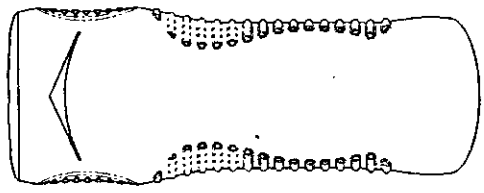


Figure 5. TriVascular Autoinjector

2. Indications for Use

The TriVascular Ovation Abdominal Stent Graft System is indicated for use in subjects diagnosed with an aneurysm in the abdominal aorta with small aortic diameters and access vessels of less than 7 mm in diameter, and having vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories,
- Non-aneurysmal proximal aortic neck:
  - with a length of at least 7 mm proximal to the aneurysm,
  - with an inner wall diameter of no less than 15.5 mm and no greater than 17.4 mm, and
  - with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm,
- Adequate distal iliac landing zone:
  - with a length of at least 10 mm, and
  - with an inner wall diameter of no less than 8 mm and no greater than 17 mm.

3. Contraindications

- Patients who have a condition that threatens to infect the graft.
- Patients with sensitivities or allergies to the device materials.

Also consider the information in Section 4 Warnings and Precautions.

4. Warnings and Precautions

CAUTION: Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

4.1. General

- The Ovation Abdominal Stent Graft System is for single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Accurate fluoroscopic imaging is required during any endovascular procedure and for proper device deployment. Implantation of this device should occur in an operating room, endovascular suite, catheterization laboratory, or similar sterile environment, with appropriately trained personnel, and suitable equipment and imaging capabilities.
- Do not use this device if the patient is unable to be evaluated using the necessary preoperative and postoperative imaging.
- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.
- Always have a qualified surgery team available during implantation or re-intervention procedures in the event that conversion to open surgical repair is necessary.

- The TriVascular Ovation Abdominal Stent Graft System should only be used by physicians and teams experienced in endovascular techniques, and who have been trained in its use. This experience should include:
  - Knowledge of the natural history of AAA and comorbidities associated with AAA repair
  - Vascular access techniques (including arterial cutdown, arteriotomy, percutaneous access, and closure techniques)
  - Nonselective and selective guidewire and catheter techniques
  - Radiographic, fluoroscopic and angiographic image interpretation
  - Embolization
  - Angioplasty
  - Endovascular stent placement
  - Snare techniques
  - Appropriate use of radiographic contrast material
  - Techniques to minimize radiation exposure
  - Expertise in patient follow-up modalities
- The long-term performance of this implant has not been established. All patients treated with this device must undergo periodic imaging to evaluate the stent graft, aneurysm size, aneurysm pulsatility, device migration, leaks, device integrity and occlusion of vessels in the treatment area. Significant aneurysm enlargement, a persistent endoleak, the appearance of a new endoleak, change in aneurysm pulsatility, device migration, reduced blood flow through the graft, and/or decrease in renal function due to renal artery occlusion should prompt further investigation into the need for further patient treatment, including additional intervention or surgical conversion. Additional patient imaging follow up should be considered for patients with devices that have effectiveness issues.
- All patients should be carefully counseled on the need for long-term follow up. The device is not recommended in patients unable or unwilling to comply with the information in Follow-up Imaging Recommendations.

4.2. Patient and Device Selection

- Access vessel diameter, vessel morphology and delivery system diameter should be compatible with vascular access techniques. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the device.
- The Ovation Abdominal Stent Graft System has not been evaluated in patients who:
  - Are pregnant or nursing;
  - Are less than 18 years old;
  - Have traumatic aortic injury, ruptured aneurysms, aneurysms pending rupture or require other emergent aorta/ aneurysm treatment;
  - Have suprarenal, thoraco-abdominal, ilio-femoral, juxtarenal, pararenal, mycotic, inflammatory or pseudo-aneurysms;
  - Have hypercoagulability, bleeding diathesis or coagulopathy;
  - Have mesenteric and/or celiac artery occlusive disease and a dominant patent inferior mesenteric artery;
  - Have connective tissue disorder or congenital degenerative collagen disease, e.g., Marfan's Syndrome;
  - Have ectatic iliac arteries requiring bilateral exclusion of hypogastric blood flow.
- Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (> 60) and/or short proximal aortic neck (< 7 mm).
- Inappropriate patient selection may result in poor device performance or device performance not otherwise in accordance with the specifications.
- This device is not recommended in patients who: have or are suspected of having an active systemic infection; cannot tolerate contrast agents necessary for intra-operative and post-operative follow up imaging; have sensitivities or allergies to the stent graft system materials, antiplatelets or anticoagulants; have creatinine level of >2.0mg/dl; have unstable angina and/or myocardial infarction (MI) or cerebral vascular accident (CVA) within 3 months prior to implantation; exceed weight and/or size limits necessary to meet imaging requirements.

4.3. Implant procedure

- Refer to section 10. Directions for Use for warnings and cautions specific to implant steps of the Ovation Abdominal Stent Graft System.
- Pre-operative planning for access and placement should be performed before opening the device packaging.
- Studies indicate that the danger of micro-embolization increases with increased procedure duration.
- Renal complications may occur from an excess use of contrast agents and/or as a result of embolic or misplaced stent graft.
- Carefully inspect the device packaging and device for damage or defects prior to use. If signs of damage or defects exist or if premature breach of the sterile barrier is observed, do not use the device.
- Minimize handling of the stent graft constrained on the delivery catheter during preparation and insertion to decrease the risk of contamination and infection.
- Do not resterilize any components of the Ovation Abdominal Stent Graft System.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Do not bend or kink the Ovation Abdominal Stent Graft System because it may damage the device and/or its components.
- Always use fluoroscopic guidance to advance the delivery system and to monitor the implant procedure, the device deployment, and the fill polymer injection / cure,
- Exercise care in handling and delivery technique to help prevent vessel rupture.
- Exercise particular care in difficult areas, such as areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels.
- If the iliac delivery system graft cover is accidentally withdrawn, the device will prematurely deploy and may be incorrectly positioned.
- Inaccurate placement or inadequate seal may result in increased risk of leakage into the aneurysm.
- Do not continue advancing any portion of the delivery system if resistance is felt during advancement of procedure accessories or of stent graft system. Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels.
- Unless medically indicated, do not deploy the stent graft components in a location that will occlude arteries necessary to supply blood flow to organs or extremities or result in an endoleak.
- Stent graft components cannot be replaced or drawn back into the delivery system, even if the stent graft component is only partially deployed.
- Inadvertent partial deployment or migration of the stent graft may require surgical removal or repair.
- Do not push or pull the delivery system after complete deployment of the proximal stent to avoid inadvertent disconnection of the polymer fill connector from the implant.
- During device use, rotate entire delivery system as a unit. Do not independently rotate catheter sheath or handle.
- Inadequate seal zone may result in increased risk of leakage into the aneurysm.
- Ensure an extra stiff wire is not inside the aortic body during injection of the fill polymer to allow conformance of the stent graft to the native anatomy when significant angulation is present.
- Use only the Autoinjector to fill the Aortic Body Stent Graft. Hand injection is not recommended and may damage the implant.
- Confirm cannulation of graft true lumen to ensure accurate placement of the contralateral limb.
- It is important to accurately size and choose the balloons to be used during device deployment. Keep the balloon inside the graft during inflation and do not over-inflate within the stent graft. Although not observed during the Ovation clinical study, inflation of the balloon outside of the graft may lead to vessel damage or rupture. Carefully follow the balloon manufacturer's inflation parameters described in the product labeling.
- Any endoleak left untreated during the implantation procedure must be carefully monitored after implantation.
- Non-clinical testing has demonstrated that the Ovation Stent Graft System is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems using the specific testing parameters listed in Section 9.4, MRI Information.

5. Adverse Events

5.1. Potential Adverse Events

Adverse events that may occur and/or require intervention include but are not limited to:

- Acute and chronic renal failure, renal microembolism, renal insufficiency, renal artery occlusion, contrast toxicity;
- Allergic reaction and/or anaphylactoid response to x–ray contrast dye, anti-platelet therapy, device materials;
- Anesthetic complications and subsequent attendant problems (aspiration);
- Aneurysm enlargement or rupture;
- Blood or bleeding events such as anemia, gastrointestinal bleeding, retroperitoneal bleeding;
- Bowel events such as bowel ischemia, infarction, bowel necrosis, colon ischemia, paralytic or adynamic ileuses, obstruction, fistulas;
- Cardiac events and subsequent attendant problems such as congestive heart failure, volume overload, arrhythmias, myocardial infarction, chest discomfort or angina, elevations in creatinine phosphokinase (CPK), hypotension, hypertension;
- Cerebral events (local or systemic) and subsequent attendant problems such as change in mental status, cerebrovascular accident (hemorrhagic or embolic), reversible ischemic neurologic deficit, nerve injury, transient ischemic attacks, paraplegia, paraparesis, paralysis;
- Death;
- Device events such as deployment or device malfunction, stent fracture, loss of stent graft system component integrity, graft twisting and/or kinking, graft material wear, dilation, erosion, puncture, endograft occlusion, migration, dislodgement, endoleak;
- Embolic and thrombotic events (with transient or permanent ischemia or infarction) such as deep vein thrombosis, thromboembolism, microembolism, thrombophlebitis, phlebothrombosis, air embolism;
- General discomfort related to the procedure;
- Generalized inflammatory response that may be associated with elevated levels of systemic mediators of inflammation, elevated temperature;
- Genitourinary complications and subsequent attendant problems such as ischemia, erosion, fistula, incontinence, hematuria, infection;
- Hepatic failure;
- Insertion and other vascular access site complications such as infection, dissection, transient fever, bleeding, pain, delayed healing, abscess formation, hematoma, dehiscence, seroma, cellulitis, nerve injury/damage, neuropathy, neuralgia, vasovagal response, pseudoaneurysm, anastomotic false aneurysm, arteriovenous fistula;
- Impotence/ sexual dysfunction;
- Lymphatic complications and subsequent attendant problems such as lymphocele, lymph fistula;
- Multi-system organ failure;
- Neoplasm;
- Operative and post–operative bleeding and hemorrhage, coagulopathy;
- Paralysis (temporary or permanent) such as paraplegia, monoplegia, paresis, spinal cord ischemia, hemiplegia, bowel or bladder incontinence;
- Pericarditis;
- Pneumothorax;
- Possible infection–urinary tract, systemic or localized, endograft;
- Pulmonary/respiratory events and subsequent attendant problems such as pulmonary insufficiency, pneumonia, respiratory depression or failure, pulmonary edema, pulmonary embolism, atelectasis, pleural effusion;
- Radiation injury, late malignancy;
- Sepsis;
- Seroma;

- Shock;
- Spinal neurological deficit;
- Surgical conversion to open repair; and/or
- Vascular spasm or vascular injury/trauma including damage to blood vessels and surrounding tissues, atherosclerotic ulcer, vessel dissection, perforation, plaque dissection, stenosis, pseudoaneurysm, vessel occlusion, embolization, ischemia, tissue loss, limb loss, gangrenous disease, worsened or new onset claudication, edema, fistula, bleeding, rupture, death.

5.2. Incident Reporting

All incidents should be reported to TriVascular immediately. To report an event, contact your local representative and/or TriVascular at the contact number provided at the end of this document.

6. Summary of Clinical Information

The Ovation Abdominal Stent Graft System pivotal clinical study is a prospective, consecutively enrolling, non-randomized multi-center clinical evaluation of the safety and effectiveness of the Ovation Abdominal Stent Graft System when used in the treatment of patients with AAA. The Ovation Abdominal Stent Graft System clinical subject population is being evaluated for: death; myocardial infarction; stroke; renal failure; respiratory failure; paralysis; bowel ischemia; procedural blood loss; successful device delivery and deployment; endoleaks; stent graft migration; AAA enlargement; AAA rupture; conversion to open repair; secondary procedures; device integrity; blood loss; duration of procedure; length of hospital stay; type of anesthesia; and type of vascular access used to implant the device.

The pivotal clinical study includes the range of aortic body sizes (20-34 mm). The data from the pivotal study were considered in the review of the HUD size (20 mm diameter) because the features of the smaller size are the same as for the rest of the product line. Although the data do not directly demonstrate the safety and effectiveness of the 20 mm device size, they are useful to characterize the product line. Regarding delivery and deployment, the mechanism is the same for the smaller and larger devices, with the french size the same (14F) for the majority of device diameters. With respect to vascular access, the pivotal clinical study included 27% of patients with access vessel sized smaller than 7mm (i.e., ≥ 4.6 mm). To date, four patients have received the 20 mm device in the Ovation Abdominal Stent Graft System clinical study. Data for two of the four were available for inclusion in the summary below.

6.1. Accountability of Pivotal Cohort

Under the HDE, data were available for 113 of the 123 subjects enrolled in the pivotal study. Of the subjects eligible for follow up, 86% (96/112) completed follow up at 1 month, 64% (42/66) completed follow up at 6 months and 50% (5/10) completed follow up at 1 year. The eligible subjects within the interval analysis window who have not completed follow-up are either pending the actual visit or the data entry had not been completed at the time of this interim report. **Table 1** below outlines interim patient accountability.

Table 1: Subject and Imaging Accountability – Ovation Treatment Group[1]

	Subject follow-up				Subjects with imaging performed (Site Reported)		Subjects with adequate imaging to assess endpoint (Site Reported)				Subject events occurring before next visit					
Interval (Analysis Window)	Eligible	Within Window Visit Pending	Clinical Follow-up	Imaging Follow Up	CT Imaging	KUB Imaging	AAA Enlargement	Endoleak	Migration	Technical Observation[2]	No Implant	Conversion to Surgery	Death	Withdrawal	Lost to Follow-up	Not Due for Next Visit
Subjects	113										0					
Events after implant but before a 1 Month visit												0	1	0	0	0
1 Month (Day 1-90)	112	16 (14%)	96 (86%)	89 (79%)	89 (79%)	87 (78%)		89 (79%)		89 (79%)						
Events after 1 Month visit but before a 6 Month visit												0	1	0	0	45
6 Month (Day 91-304 days	66	24 (36%)	42 (64%)	41 (62%)	39 (59%)	40 (61%)	36 (55%)	38 (58%)	40 (61%)	37 (56%)						
Events after 6 Month visit but before a 12 Month visit												0	0	0	0	56
12 Month (≥ 305 days)	10	5 (50%)	5 (50%)	5 (50%)	5 (50%)	4 (40%)	4 (40%)	5 (50%)	5 (50%)	5 (50%)						

[1] At the time of this interim analysis, sample size varies for each of the time points above and in the following tables due to subject availability for follow up, as well as the ongoing data entry process.
[2] Technical observations assessed by imaging include stent graft kinking and stent graft stenosis.

6.2. Study Population Demographics and Baseline Parameters

Baseline data regarding demographics, medical history, aneurysm characteristics and devices sizes used are summarized in **Tables 2-8**.

Table 2: Baseline Demographics

Demographic	Treatment Group
Age (at enrollment)	
Average Years ± SD	73.5 ± 7.6
Range	54, 95
Gender	
Male % (n/N)	85.8% (97/113)
Female % (n/N)	14.2% (16/113)

Table 3: Medical History

Comorbid Conditions	Treatment Group % (n/N)
Cardiovascular Disease	
Coronary Artery Disease	38.9% (44/113)
Valvular Heart Disease	6.2% (7/113)
Angina	7.1% (8/113)
Cardiomyopathy	4.4% (5/113)
Congestive Heart Failure	6.2% (7/113)
Myocardial Infarction	15.9% (18/113)
Arrhythmia	21.2% (24/113)
Hypertension	80.5% (91/113)
Hypotension	0.9% (1/113)
Hyperlipidemia	66.4% (75/113)
Peripheral Vascular Disease, Stroke and Aneurysm History	
Peripheral Vascular Disease	17.7% (20/113)
Carotid Artery Disease	10.6% (12/113)
Transient Ischemic Attack (TIA)	4.4% (5/113)
Stroke (CVA)	6.2% (7/113)
Family History of Aneurysms	3.5% (4/113)
Aneurysms (AAA)	100% (113/113)
Pulmonary History	
Chronic Obstructive Pulmonary Disease (COPD)	26.5% (30/113)
Smoking (past smoking history not reported for all subjects)	42.5% (48/113)
Gastrointestinal, Genitourinary, Reproductive History	
Renal Failure/Insufficiency	11.5% (13/113)
Diabetes	21.2% (24/113)
Alcohol Abuse	1.8% (2/113)
Hematological Problems (hemorrhage, coagulopathy disorder, anemia, platelet disorder)	8.0% (9/113)
Other Significant Medical Condition	68.1% (77/113)

Table 4: Baseline Anatomical Characteristics

Characteristic	Treatment Group
Aortic Neck Length (mm)	
N	105
Mean ± SD	25.6 ± 12.3
Median	24
Min, Max	7, 76
Aortic Neck Diameter (mm)	
N	60*
Mean ± SD	22.8 ± 3.2
Median	22.4
Min, Max	17, 30

Characteristic	Treatment Group
Aortic Neck Angle (degrees)	
N	86*
Mean ± SD	18.8 ± 14.4
Median	15
Min, Max	0, 60
Right External Iliac Diameter (mm)	
N	97
Mean ± SD	8.12 ± 1.72
Median	8
Min, Max	4.4, 12.5
Left External Iliac Diameter (mm)	
N	97
Mean ± SD	*8.32 ± 1.79*
Median	8.2
Min, Max	5, 13
AAA Maximum Diameter (mm)	
N	105
Mean ± SD	55.1 ± 8.2
Median	54
Min, Max	40, 94
AAA Maximum Diameter (mm)	**Treatment Group % (*n/N*)**
<50 mm	13.3% (14/105)
50 mm to 59 mm	73.3% (77/105)
60 mm to 69 mm	8.6% (9/105)
70 mm to 79 mm	1.9% (2/105)
80 mm to 89 mm	1.0% (1/105)
≥ 90 mm	1.9% (2/105)

*N represents data available as of the date of the report. Data entry was in process for these data points in 8 subjects at the time of the report.

A total of 113 Aortic Bodies (**Table 5**) and 251 Iliac Limbs (**Table 6**) were implanted in 113 subjects. A total of 21 subjects received Iliac Limbs as extensions (**Table 7**).

Table 5: TriVascular Ovation Aortic Bodies Implanted

Aortic Body (Diameter, mm)	Number of Devices % (n/N)
34	9.7% (11/113)
29	27.4% (31/113)
26	36.3% (41/113)
23	24.8% (28/113)
20	1.8% (2/113)

Table 6: TriVascular Ovation Iliac Limbs Implanted

Iliac Limb (Diameter, mm)	Number of Devices % (n/N)
22	7.6% (19/251)
18	14.0% (35/251)
16	16.3% (41/251)
14	36.3% (91/251)
12	19.5% (49/251)
10	6.4% (16/251)

Table 7: TriVascular Ovation Iliac Limb Extensions Implanted

Iliac Limb Extension (Diameter, mm)	Limb Extension Number of Devices % (n/N)
22	8.0 %(2/25)
18	20.0% (5/25)
16	12.0% (3/25)
14	32.0% (8/25)
12	28.0% (7/25)

A total of 21 subjects were implanted with >2 iliac limbs.

Table 8: Total Number of Devices Implanted at Initial Procedure

Number of Devices Implanted at Initial Procedure	Number of Subjects % (n/N)
1	0% (0/113)
2	0% (0/113)
3	81.4% (92/113)
4	15.1% (17/113)
5	3.5% (4/113)
≥6	0% (0/113)

6.3. Safety and Probable Benefit Information

Serious adverse events in the clinical study report subject cohort available at the time of report date are presented in **Table 9**. A serious adverse event is defined as one that suggests a significant hazard or side effect, regardless of the investigator or sponsor's opinion on the relationship to the investigational product. This includes, but may not be limited to, any event that is fatal; is life-threatening; requires or prolongs (>48 hours) inpatient hospitalization; is a persistent or significant disability or incapacity; and/or is considered an important medical event.

Table 9: Serious Adverse Events (SAE)*

Serious Adverse Event Category	(0-30 Days)	(31-360 Days)
Blood and Lymphatic	2	0
Cancer	0	1
Cardiac	2	2
Device	0	2
Gastrointestinal	1	0
Genitourinary	1	0
Infection (other than wound)	0	1

Serious Adverse Event Category	(0-30 Days)	(31-360 Days)
Neurological	0	0
Orthopedic	0	0
Pulmonary	2	0
Vascular and Aortic	0	0
Wound	0	0
Other**	14	6

*No SAEs occurred in subjects implanted with the 20mm device.
**Currently includes chronic anemia; air in intestine; heavy dyspnea; anaphylactic shock; polymer leak from main body of stent graft; vasospasm; heparin induced thrombocytopenia; gastrointestinal bleed; abdominal sepsis; acute leukemia; cutaneous rash; cerebral cramps/coma; dilated biliary ducts; pseudoaneurysm; nausea/vomiting; anemia; respiratory distress; hypoxia; hematochezia.

Two (2) serious adverse events in the "other" category (polymer leak from the aortic body of the stent graft and anaphylactic shock) were reported by the investigator for one subject. The subject was receiving an implant of a 26mm TriVascular Ovation Abdominal Stent Graft System and fill polymer discharge occurred due to a disconnection of the fill tube that injects the fill material polymer into the aortic body stent graft. There were no embolic consequences and the aneurysm was successfully excluded. The subject was transferred to ICU post procedure. On post-operative day 16, the subject experienced disseminated intravascular coagulation and abdominal sepsis and expired the following day (refer to **Table 11** below). Upon review by the Data Safety Monitoring Board (DSMB), the members recommended that the events be reported to FDA as an unanticipated adverse device effect (UADE). In response, TriVascular modified a component of the delivery system and its connection to the delivery system to address the fill tube disconnection. No additional UADEs or fill polymer discharge events have been reported to date.

The device events reported under the HDE are presented in **Table 10**.

Table 10: Device Event Reports*

Description	0-30 Days	31-365 Days
Technical Failure	0	
Endoleaks (Type I and/or III)	1	0
Migrations	0	0
AAA Enlargement	0	1
Rupture	0	0
Device Integrity	0	1
Secondary Interventions	1	2
Conversion to Open Surgical Repair	0	0

*No device events occurred in subjects implanted with the 20mm device.

Technical success is defined as successful delivery and deployment of one aortic body and two iliac limbs. As presented in **Table 10**, there are no technical failures and all subjects received a minimum of one aortic body and two iliac limbs. In one subject, a Type IA (proximal) endoleak was reported at the 1 month follow up and successfully treated with coil embolization several weeks later with no clinical sequelae. In another subject, an iliac limb stenosis was reported at the 30 day follow up and considered by the investigator to be procedure related. The stenosis was successfully treated with angioplasty and stent placement with no clinical sequelae. In a third subject, a device thrombus was considered by the investigator to be related to the study device. The subject was successfully treated with lysis and stenting with no clinical sequelae. Upon review of the imaging and procedural information for this case, the Clinical Events Committee (CEC) determined that this event was procedure related and not device related. In a fourth subject with a Type II endoleak, an increase of >5mm in the diameter of the aneurysm was reported. The imaging is being re-evaluated by the core lab due to the challenging anatomic morphology. No treatment or adverse sequelae has been reported. A single strut fracture in the proximal stent was identified in one study subject with no clinical sequelae and continued aneurysm exclusion. The evaluation of the source of the fracture identified that the probable root cause is an isolated incident related to a material void in the nitinol raw tubing and is not related to device design.

Table 11: Mortality

Mortality	0-30 Days	31-365 Days
All Cause	N/A	1
AAA Related	1	0

Two (1.8%) subjects died during the study. One subject died from disseminated intravascular coagulation (DIC) and abdominal sepsis as described under **Table 9** above. One subject died from reported "cerebral cramps", coma, and gastrointestinal bleed at 178 days post study procedure. These events were considered by the investigator to be related to pre-existing conditions including liver cirrhosis, and cerebral, coronary and peripheral artery disease.

Of the four patients who have received the 20 mm device in the Ovation Abdominal Stent Graft System clinical study, one Type II endoleak was reported for one subject with no treatment or adverse sequelae reported. No additional events have been reported in the other subjects receiving a 20 mm device.

7. Patient Selection and Treatment

7.1. Individualization of Treatment

The TriVascular Ovation Abdominal Stent Graft System must be selected in a size appropriate to the patient's anatomy. Proper sizing of the device is the responsibility of the physician. The sizing options for the device are detailed in **Table 12** Patient Sizing Information.

Table 12. Patient Sizing Information

Aortic Body	
Stent Graft Diameter, mm	**Aortic ID, mm**
20	16-17

Iliac Limb / Extension	
Stent Graft Diameter, mm	**Iliac ID, mm**
18	16-17
16	14-15
14	12-13
12	10-11
10	8-9

* At the intended proximal sealing ring location. Ensure adequate oversizing of the proximal stent at its anchoring location.

CAUTION: Proper sizing of the Ovation Abdominal Stent Graft is the responsibility of the physician. This stent graft sizing incorporates the recommended device oversizing for anatomical dimensions and was based on *in-vitro* test data.

The recommended overall length of the deployed, implanted system should extend from the lowest renal artery to just above the internal iliac bifurcation. If pre-operative case planning measurements are not certain, ensure that all potential stent graft lengths and diameters are available to complete the procedure.

Considerations for patient selection include but are not limited to:

- Patient's age and life expectancy
- Co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity)
- Patient morphologic suitability for endovascular repair
- Patient's suitability for open surgical repair

During the case planning process, TriVascular may consult with physicians in their efforts to determine appropriate stent graft sizing based on the physician's assessment of the patient's anatomical measurements. The benefits and risks previously described must be considered for each patient before use of the Ovation Abdominal Stent Graft System.

7.2. Specific Patient Populations

The Ovation Abdominal Stent Graft System has not been evaluated in patients who:

- Are pregnant or nursing;
- Are less than 18 years old;
- Have traumatic aortic injury or rupture or require other emergent aorta/ aneurysm treatment;
- Have suprarenal, thoraco-abdominal, mycotic or pseudo-aneurysms;
- Have acutely ruptured aneurysms or aneurysms pending rupture;
- Have hypercoagulability, bleeding diathesis or coagulopathy;
- Have ilio-femoral, thoracic or inflammatory aneurysms;
- Have juxtrarenal AAA;
- Have pararenal AAA;
- Have mesenteric and/or celiac artery occlusive disease and a dominant patent inferior mesenteric artery;
- Have connective tissue disorder or congenital degenerative collagen disease, e.g., Marfan's Syndrome.

8. Patient Counseling Information

Prior to treatment, the physician should review with the patient the risks and benefits of this endovascular procedure, including:

- Risks and benefits of aneurysm repair given the patient's age and life expectancy;
- Risks, benefits and differences of open surgical repair;
- Risks, benefits and differences of endovascular repair;
- Risks related to noninterventional treatment (medical management);
- Risks of aneurysm rupture as compared to the risk of endovascular repair;
- The long-term safety and effectiveness of endovascular repair has not been established;
- The importance of life-long, regular follow up to assess patient's health status and the stent graft performance;
- Subsequent endovascular or open surgical repair of the aneurysm may be required;
- Patient with specific clinical findings (e.g. endoleaks, enlarging aneurysms) should be monitored closely;
- Signs to seek prompt medical attention (including limb occlusion, aneurysm enlargement, or rupture).

TriVascular recommends that the physician disclose to the patient, in written form, all risks associated with treatment using the Ovation Abdominal Stent Graft System. Details regarding risks occurring during and after implantation of the device are provided in Section 5, Adverse Events. Additional counseling information can be found in the Patient Information Booklet.

9. How Supplied

The Ovation Abdominal Stent Graft System is comprised of the aortic body stent graft/ delivery system, the iliac limbs and iliac extensions stent graft/ delivery system, the fill polymer kit, and the autoinjector.

The stent grafts are available in the following sizes and configurations.

Table 13. Ovation Aortic Body Stent Graft sizes

Stent Graft Proximal Diameter	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
20 mm	57 cm	14 F	80 mm

Table 14. Ovation Iliac Limb sizes

Stent Graft Proximal Diameter	Stent Graft Distal Diameter	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
14 mm	10 mm	53 cm	13 F	80 mm
	10 mm			100 mm
	10 mm			120 mm
	10 mm			140 mm
	12 mm			80 mm
	12 mm			100 mm
	12 mm			120 mm
	12 mm			140 mm
	14 mm			80 mm
	14 mm			100 mm
	14 mm			120 mm
	14 mm			140 mm
	16 mm		14 F	80 mm
	16 mm			100 mm
	16 mm			120 mm
	16 mm			140 mm
	18 mm			80 mm
	18 mm			100 mm
	18 mm			120 mm
	18 mm			140 mm

Table 15. Ovation Iliac Extension sizes

Stent Graft Proximal & Distal Diameters	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
10 mm	53 cm	13 F	45 mm
12 mm			
14 mm			
16 mm			
18 mm		14F	

9.1. Ovation Stent Graft & Delivery Systems

Contents are supplied STERILE and non-pyrogenic using an ethylene oxide (EO) process.

- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damaged or if the sterilization barrier has been damaged or broken.
- Do not use after the expiration date printed on the label.
- Store in a cool, dry place.
- **For single patient use only.** Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of the product and packaging in accordance with hospital, administrative and/or local government policy.

9.2. Fill Polymer Kit & Autoinjector

Contents are supplied STERILE using an E-beam sterilization process. The Fill Polymer Kit is non-pyrogenic.

- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damaged or if the sterilization barrier has been damaged or broken.
- Do not use after the expiration date printed on the label.
- Store in a cool, dry place.
- **For single patient use only.** Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of the product and packaging in accordance with hospital, administrative and/or local government policy.

10. Clinician Use Information

10.1. Physician Training

CAUTION: Always have a vascular surgery team available during implantation or re-intervention procedures in the event that conversion to open surgical repair is necessary.

CAUTION: The Ovation Abdominal Stent Graft System should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device.

The recommended skill/ knowledge requirements for physicians using the Ovation Abdominal Stent Graft System are outlined below. If you have questions about the product or sizing, contact TriVascular via the information in the back of this manual.

Patient Selection:

- Knowledge of the natural history of abdominal aortic aneurysm (AAA) and co-morbidities associated with AAA repair.
- Knowledge of radiographic image interpretation, device selection and sizing.

A multi-disciplinary team that has combined procedural experience with:

- Femoral cutdown, arterial bypass, arteriotomy, and repair
- Percutaneous access and closure techniques
- Non-selective and selective guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty

- Endovascular stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

10.2. Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and contact your TriVascular representative for return information.

10.3. Materials Required

Table 16. Equipment and Ancillary Items

Required Equipment	Ancillary Equipment
TriVascular Ovation Abdominal Stent Graft Aortic Body preloaded in Delivery System	
TriVascular Ovation Abdominal Stent Graft Iliac Limbs (2) preloaded in Delivery Systems	
	TriVascular Ovation Abdominal Stent Graft Iliac Extensions preloaded in Delivery Systems
TriVascular Fill Polymer Kit	Timer or clock
TriVascular Autoinjector	
Imaging Equipment with capability to record and recall all imaging • Imaging table, or operating room table designed for use with C-arm • Fluoroscopy capability • Digital Subtraction Angiography (DSA) capability • Appropriate personnel protection equipment for fluoroscopy	Video recorder Power injector with associated supplies
Angiography and exchange catheters Assortment of adequate sizes (0.035" compatible) and assorted lengths	
Guidewires: Assorted sizes of physician's preference, 0.035" compatible, 150 cm compatible	
Contrast media	
Heparinized saline and flushing syringes	
Vascular instruments and supplies	Endovascular supplies • 3-way stopcocks • Tuohy-Borst adaptors Optional: • Introducer sheaths < 35 cm length • Range of appropriately sized (balloon diameter and length and shaft length) angioplasty balloons: - 12 mm diameter non-compliant balloon(s) for possible ballooning of iliac limb to aortic body junction; - Non-compliant balloons for treatment of and equivalent size to the distal iliac diameter; - Compliant and non-compliant balloons for treatment of and equivalent size to the aortic diameter. • Embolization devices such as coils

10.4. MRI Information

MR Conditional

MR Conditional

The Ovation Abdominal Stent Graft System was determined to be MR Conditional.

Non-clinical testing demonstrated that the Ovation Abdominal Stent Graft System is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 1.5 or 3.0-Tesla
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 4 W/kg in the first level controlled mode for a maximum scan time of 15 minutes

MRI-Related Heating

In non-clinical testing, the Ovation Abdominal Stent Graft System produced the following temperature rises during MRI performed for 15-min of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

	1.5-Tesla	*3-Tesla*
MR system reported, whole body averaged SAR	2.9-W/kg	2.9-W/kg
Calorimetry measured values, whole body averaged SAR	2.1-W/kg	2.7-W/kg
Highest temperature change	+1.9°C	+2.3°C

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Ovation Abdominal Stent Graft System. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	8,875-mm^2	353-mm^2	12,026-mm^2	628-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

The artifacts extend approximately 4- to 6-mm from the metallic portion of the device, both inside and outside the device lumen.

11. Directions for Use

11.1. Patient Preparation

- In general, utilize similar patient pre-operative steps as for standard AAA open repair: fasting, bowel preparation, and prophylactic antibiotic regimens. Prepare and drape the patient for an open surgical AAA procedure, in the event that conversion to open repair is required.
- The patient anesthesia protocol utilized during the endovascular procedure is left to the discretion of the implanting physician and anesthesiologist. General anesthesia, regional anesthesia, or local anesthesia combined with conscious sedation are all successfully utilized during endovascular procedures.
- Appropriate procedural imaging is required to successfully position the TriVascular Ovation Abdominal Stent Graft System in the vasculature and to assure appropriate arterial wall apposition. Always use fluoroscopy

for guidance, delivery, fill polymer injection / cure, and observation of the TriVascular Ovation Abdominal Stent Graft System within the vasculature.

11.2. General Implant Procedure Precautions

- Do not kink the delivery catheters. Doing so may cause damage to the delivery catheters and the TriVascular Ovation Abdominal Stent Graft System.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocols. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the stent graft constrained on the delivery catheter during preparation and insertion to decrease the risk of contamination and infection.
- Do not continue advancement of the guidewire or delivery catheter if resistance is felt, as vessel or delivery catheter damage may occur. Stop and assess the cause of the resistance.
- Inadvertent partial deployment or migration of the stent graft may require surgical removal or repair.

11.3. Implant Procedure and Deployment Instructions

Vascular Access

1	Establish bilateral access using standard interventional technique.
2	Place an angiographic catheter suprarenal from contralateral side and perform angiographic assessment of patient's vasculature.
3	Identify reference positions for renal arteries.
4	Insert a 0.035" guidewire on ipsilateral side and position appropriately.

Delivery System(s) Preparation

1	Inspect all packaging for damage or loss of sterile barrier. If damage is observed, replace with another device.
2	Remove delivery system from its sterile package.
3	Using sterile technique, place delivery system onto sterile field.
4	Inspect delivery system for damage; if present, replace device.
5	For the aortic body only, carefully retract delivery system outer sheath approximately 1 cm to facilitate retraction within the vasculature. Advance catheter sheath to its original position. If sheath retraction is difficult, replace device.
6	Flush delivery sheath with heparinized saline using the sheath flush port. Ensure the Polymer Fill Tube contains no liquid after flushing the Aortic Body Stent Graft Catheter sheath. If liquid is identified, replace the Aortic Body Stent Graft Catheter.
7	Flush guidewire lumen (blue cap) with heparinized saline using guidewire flush port on handle while placing a finger over the open end of the guidewire port. Close blue cap.

Aortic Body Insertion and Deployment

1	Remove introducer sheath from ipsilateral access site (if applicable).
2	Load aortic body delivery system over guidewire.
3	Activate hydrophilic coating on delivery sheath exterior by gently wiping surface with heparinized saline.
4	Using continuous fluoroscopic guidance, insert delivery system into vasculature and advance it until the implant marker coils are about 1 cm proximal to the intended landing site.
5	Orient aortic body laterally within aneurysm sac until nosecone radiopaque marker or fill tube radiopaque marker is toward patient's ipsilateral side. ***CAUTION: Rotate entire delivery system as a unit. (Do not independently rotate catheter sheath or handle.)***
6	Under fluoroscopic guidance, retract delivery system outer sheath until the sheath retraction knob meets handle.
7	Verify implant marker coil positioning is just proximal to the landing site. If necessary, carefully reposition delivery system.
8	Deploy first segment of proximal stent: turn first stent release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.

9	Orient C-Arm to align implant marker coils to achieve orthogonality of view.
10	Precisely position implant marker coils at proximal landing site. Using contrast injections, as needed, confirm position of the implant relative to renal arteries.
11	Retract angiographic catheter away from proximal stent, if necessary.
12	Deploy remainder of proximal stent: turn second stent release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.
WARNING: DO NOT push or pull the delivery system after complete deployment of the proximal stent to avoid inadvertent disconnection of the polymer fill connector from the implant.	
WARNING: To allow conformance of the stent graft to the native anatomy when significant angulation is present, ensure that an extra stiff wire is not inside the aortic body during injection of the fill polymer.	

Fill Polymer Preparation

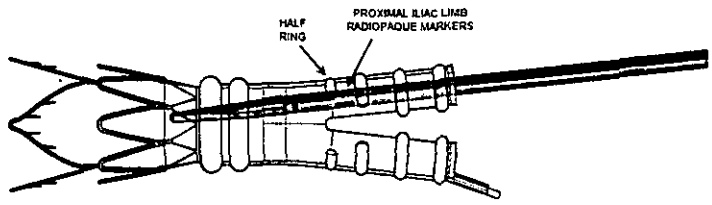
1	Using sterile technique, place fill polymer kit and autoinjector onto sterile field.
2	Open both fill kit syringe valves, and transfer contents between syringes for a minimum of 15 full strokes. Completely transfer contents into syringe with green band and close both stopcocks. Remove tear tab and disconnect full syringe.
WARNING: Should an error occur in the timing, mixing, or transfer, discard the fill polymer. Start mixing with a new fill polymer kit.	
WARNING: Injection of the fill polymer should occur immediately after mixing. If injection of the fill polymer has been delayed 3 or more minutes after mixing, discard the fill polymer. Start mixing with a new fill polymer kit.	

Fill Polymer Injection

WARNING: DO NOT push or pull the delivery system after complete deployment of the proximal stent to avoid inadvertent disconnection of the polymer fill connector from the implant.	
WARNING: Use only the Autoinjector to fill the Aortic Body Stent Graft. Hand injection is not recommended and may damage the implant.	
1	Remove green fill cap from polymer injection port on handle.
2	Attach full syringe to polymer injection port on handle.
3	Firmly hold filled syringe stationary and push autoinjector over plunger, ensuring that the autoinjector is placed over the "shoulders" of the syringe body. Rotate autoinjector 90 degrees to lock (confirmed with an audible "click"). Fill polymer will begin filling aortic body.
4	Note the time, or start a timer, when the Autoinjector is attached to the syringe.
5	Using fluoroscopy, intermittently observe filling of graft with radiopaque fill polymer.
WARNING: During fill polymer injection and cure, observe the delivery system and/or syringe for inadvertent disconnection or fill polymer spill. Radiopaque marker movement and/or rapid emptying of the fill polymer syringe may be indications that the fill polymer is not filling the stent graft. If this is observed, immediately disconnect the Autoinjector from the fill polymer syringe.	

Contralateral Limb Insertion and Deployment

1	Refer to Delivery System(s) Preparation for delivery system preparation steps.
2	Cannulate the contralateral lumen with a guidewire.
	CAUTION: Confirm cannulation of graft true lumen to ensure accurate placement of the contralateral limb.
3	Use imaging techniques to locate the contralateral internal iliac artery.
4	Confirm appropriate size (diameter and length) of iliac limb selected for contralateral side, and prepare iliac limb delivery system (per above instructions).
5	Maintaining guidewire position, remove angiographic catheter and introducer sheath from contralateral access site (if applicable).
6	Load iliac limb delivery system over guidewire.

7	Using continuous fluoroscopic guidance, insert iliac limb delivery system into vasculature until proximal iliac limb radiopaque markers align with the ½ ring of the aortic body (most proximal ring). 
8	Confirm distal iliac limb radiopaque markers are at the appropriate location.
9	Retract sheath to deploy iliac limb while maintaining catheter handle position.
10	Maintain position of sheath and use catheter handle to retract nosecone to sheath.
11	Remove iliac limb delivery system from vasculature while maintaining guidewire position. Re-insert angiographic catheter and advance to suprarenal aorta.

Aortic Body Catheter De-Mate and Withdrawal

1	A minimum of 19 minutes after attaching the Autoinjector to the syringe, disconnect Autoinjector from aortic body delivery system, holding the Autoinjector tightly to control its force once it is unlocked from the shoulders of the syringe. ***WARNING: Do not disconnect the delivery system before 19 minutes to prevent potential release of fill polymer.***
2	Release catheter from aortic body: turn third release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.
3	Using fluoroscopy, carefully withdraw inner catheter until fill lumen disengages from stent graft. The radiopaque marker band on the polymer fill port should move away from stent graft. ***WARNING: If resistance is encountered during catheter withdrawal, STOP. Identify cause of resistance and resolve prior to continuing withdrawal. Catheter rotation may be sufficient to overcome resistance.***
4	While maintaining guidewire position, use catheter handle to retract nosecone to tip of delivery system outer sheath.
5	Remove the aortic body delivery system.

Ipsilateral Limb Insertion and Deployment

1	Refer to Delivery System(s) Preparation for delivery system preparation steps.
2	Follow the appropriate procedural steps for ipsilateral limb deployment as previously described in Contralateral Limb Insertion and Deployment.

Deployment Completion

1	Verify aneurysm exclusion. Perform angiography from proximal landing site to distal landing sites.
2	Although not required as part of the implant procedure, angioplasty balloons of appropriate sizes (diameter equivalent to the vessel size) may be used to improve aneurysm exclusion or to improve the stent graft lumen. ***WARNING: It is important to accurately size the balloons and not over-inflate within the stent graft. Carefully follow the balloon manufacturer's inflation parameters described in the product labeling.*** • Prepare balloon catheters and other adjunctive devices to be used according to the manufacturer's Instructions For Use. • Iliac limb/ aortic body junction: The junction may be ballooned using a 12 mm non-compliant balloon, inflated to no more than 5 atm. The "kissing balloon" technique may be utilized at this location. • Distal iliac: The area may be ballooned using a non-compliant balloon the same diameter as the distal iliac diameter. ***WARNING: Do not balloon the iliac limb/ aortic body junction or the distal iliac with a compliant balloon.***

	• After removal of the angiographic catheter (if present), the proximal aortic body may be ballooned before delivery system removal with a compliant balloon of the same diameter as the proximal aortic diameter. A non-compliant balloon may be used in the aortic body only after the delivery system is removed. ***CAUTION: It is not recommended to balloon prior to 15 minutes after completion of the final polymer mix. Ballooning prior to 15 minutes could damage the sealing rings.***
3	If no other interventions are required and aneurysm exclusion has been verified, remove the angiographic catheter and maintain guidewire position(s). If extension of the iliac is required, proceed with the Iliac Extension Insertion and Deployment steps below.
4	Remove guidewires and introducer sheaths. Close vascular access.

Iliac Extension Insertion and Deployment

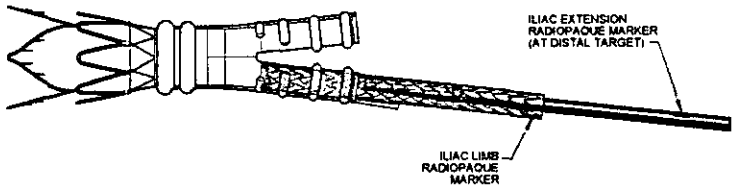
1	Using the radiopaque markers on the distal end of the iliac limb as a target and using standard endovascular techniques, cannulate the iliac limb lumen with a guidewire (if necessary).
2	Determine the amount of extension required. If 20mm or less, use of a straight distal extension is recommended. Refer to the table below for the distal straight extension diameters (Iliac Extension Sizes, 45mm length) recommended for use with each iliac limb distal diameter.

		Iliac Extension Size (Straight, 45mm length)				
		10	12	14	16	18
Iliac Limb Distal Diameter	10	X	X	X		
	12		X	X	X	
	14			X	X	X
	16				X	X
	18					X
		20mm Maximum allowable extension				

3	To use an iliac limb as an extension, refer to the table below. Based on the iliac limb distal diameter and the amount of extension required, select the appropriate extension component length.

Iliac Limb Distal Diameter (mm)	Amount of Extension Required (mm)	Extension Component Length (mm)
10 12	Up to 50	80
	51 - 70	100
	71 - 90	120
	91 - 110	140
14 16 18	Up to10 **	80 **
	11 - 20	100
	21 - 40	120
	41 - 60	140
** Diameter of extension must be ≥ distal diameter of iliac limb		

3	Prepare the extension delivery system (per above instructions)
4	Maintaining guidewire position, remove angiographic catheter and introducer sheath from access site (if applicable).
5	Load the delivery system over the guidewire.
6	Insert the delivery system into the vasculature until the distal radiopaque marker of the extension is aligned at the distal target. Use continuous fluoroscopic guidance to ensure proper positioning of the stent graft.

7	Verify the appropriate position of the extension relative to the iliac limb and vasculature. 
8	Retract sheath to deploy stent graft while maintaining catheter handle position.
9	Maintain position of sheath and use catheter handle to retract nosecone to sheath.
10	Remove delivery system from vasculature while maintaining guidewire position.
11	Advance and inflate an appropriate size non-compliant balloon in the overlap region. Follow the manufacturer's recommended method for size selection, preparation, and use of balloons.
12	Re-insert angiographic catheter and advance to the suprarenal aorta. Perform deployment completion angiography as described above.

12. Follow-up Imaging Recommendations

TriVascular recommends the following imaging schedule for patients treated with the Ovation Abdominal Stent Graft System. The appropriate follow up imaging and imaging modalities for a particular patient are the responsibility of the clinician.

The imaging schedule outlined below is the same schedule used in the Ovation Abdominal Stent Graft System clinical evaluation.

Table 17. Recommended patient imaging schedule

	Contrast Enhanced Spiral CT*	Abdominal X-rays**
Pre-procedure (baseline)	X	
Pre-discharge		X
1 month	X	X
6 month	X	X
12 month (annually thereafter)	X	X

* Abdominal/ Pelvic. Used to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, stent graft patency, AAA size, occlusion of branch vessels, and endoleak (including source and type if present).

** AP, lateral, left oblique and right oblique views. Used to assess the presence of stent fracture. Ensure the entire device is captured on images for device assessment.

Patients should be counseled on the importance of adhering to the recommended follow-up schedule during the first year and annually thereafter. More frequent follow-up may be required for some patients based on clinical evaluation.

12.1. Non-Contrast CT

For patients with impaired renal function or those who are allergic to contrast medium, a spiral CT without contrast may be considered to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration and size of the AAA with diameter and volume measurements.

12.2. Duplex Ultrasound

For patients with impaired renal function or those who are allergic to contrast medium, a color-duplex ultrasound may be considered to assess size of AAA with diameter, endoleaks, and stent graft occlusion and stenosis.

12.3. MRI or MRA

Patients with impaired renal function, i.e., renal insufficiency, may also be considered for magnetic resonance imaging or angiography (MRI, MRA) in facilities that have expertise in this area. Artifact may occur related to the stent, and care should be used to insure adequate imaging of the outer aneurysm wall to assess AAA size. Volume measurement may be helpful if the aneurysm is not clearly shrinking. If there are concerns regarding imaging of calcified areas, fixation sites, or the outer wall of the aneurysm sac, adjunctive CT without contrast may be needed. Specific information on MRI can be found in Section 10.4 MRI Information.

TriVascular recommends contrast enhanced Spiral CT data for reconstruction. The requirements are outlined in **Table 18**.

Patient motion should be avoided during scan. If possible, avoid scanning non-patient objects in field of view. Do not change patient position, table height, or field of view during scan. If patient moves, repeat the study in its entirety.

Table 18. Spiral CT requirements

	Minimum Protocol	High Resolution Protocol (Recommended)
Scan Mode	Helical	Helical
Scan Parameters	110-140 kVp, Auto mAs or 170-400 mA scan time of 0.5 sec	110-140 kVp, Auto mAs or 170-400 mA scan time of 0.5 sec
Slice Thickness	3 mm	0.625 – 2 mm
Slice Interval	3 mm	0.625 – 2 mm
Pitch	0.984:1	0.984:1
Superior Extent AAA	2 cm above celiac artery origin	2 cm above celiac artery origin
Inferior Extent AAA	Pre-op: Lesser trochanter of femurs to include femoral bifurcations Post-op: At least 2 cm distal to the lowest hypogastric artery origin	Pre-op: Lesser trochanter of femurs to include femoral bifurcations Post-op: At least 2 cm distal to the lowest hypogastric artery origin
Contrast	Standard per Radiology Department	Standard per Radiology Department
Volume	80 ml contrast with 40 ml saline flush or Standard Contrast Volume with Saline Flush per Radiology Department	80 ml contrast with 40 ml saline flush or Standard Contrast Volume with Saline Flush per Radiology Department
Rate	4 ml/sec	4 ml/sec
Scan Delay	ROI – threshold 90-100 HU in aorta	ROI – threshold 90-100 HU in aorta
Field of View	Large Body	Large Body
Reconstruction Algorithm	Standard	Standard

13. Device Registration

The following supplementary documentation is included with the Ovation Abdominal Stent Graft System:

- Device Implant Card: This card contains physician, stent graft and hospital information. Physicians should complete this card and instruct the patient to keep it in their possession at all times. The patients should refer to this card anytime they visit additional health practitioners, particularly for additional diagnostic procedures (e.g. MRI).
- Device Tracking Documents: The documentation is to be completed by the hospital staff and forwarded to TriVascular for the purposes of tracking all patients who received an Ovation Abdominal Stent Graft System (as required by Federal Regulation).

14. Symbols

	Batch Code
	Use by
	Contents
	Non-pyrogenic
	Consult Instructions for use
	MR Conditional
	Upper limit of temperature
	Do not reuse
	Do not resterilize
	Keep dry
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Authorized Representative in the European Community
	Manufacturer

Manufacturer:

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For patent coverage, see www.TriVascular.com.